The National Board of Health and Welfare
Public Health Section
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NEW RULES FOR MARKING TOBACCO PACKAGES

BACKGROUND:

In 1987, after a decision by the Director General of the National Board of Health and Welfare at that time, work was commenced on renewing the system of warning texts on tobacco packages. The reason was the appraisal that we, today, - compared with 1976 when the present system was developed - have considerably greater knowledge about and look more seriously upon the health risks of tobacco. This toughened attitude should be reflected in a development of the warning text system.

The cooperation of the National Board regarding marking rules etc. within SIS (the Standardization Commission in Sweden) has brought about minor changes in the rules for declarations of contents. The greatest change is that "tar", in the future, shall be reported *without* nicotine, instead of including nicotine which is the case today. Nicotine is reported separately. The change entails an adaptation to the rules of the EC.

DECISION:

Director General, Claes Örtendahl, commissioned Deputy Director General, Olof Edhag (ÖdM) to make a decision in this matter. At the presentation of the matter on 3 December 1990, ÖdM decided, in principle, to implement new warning texts and to change rules for declarations of contents on tobacco packages (public notice concerning the change in public notice SOSFS 1976:32 about warning text and declaration of contents on tobacco products) in accordance with the below. A final decision (regarding even new rules for the declarations of contents) was made by ÖdM on 9 January 1991, after, among other things, the final originals for the new texts had been produced.

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I. WARNING TEXTS

MATERIAL THE DECISION WAS BASED ON

* Memo 26 November 1987, "New warning texts on tobacco packages by 1990"

* Memo 20 December 1989, "New warning texts on tobacco packages - proposal from a consultative group"

* Compilation of opinions concerning the proposal about new warning texts on tobacco packages, 20 February 1990 (complemented by opinions sent in late by the Cancer Fund and member of the scientific council, Prof. Ragnar Rylander).

* Minutes from the final meeting with the consultative group on 20 August 1990.

* Memo 7 November 1990, "New rules for marking tobacco packages?"

WHAT THE DECISION MEANS IN DETAIL:

1. Increasing the scope of the warning text system

a) A common set of varying texts for all tobacco products that are intended to be smoked.

Commentary: Newer research has weakened the basis for the assumption that different types of smoking implements decisively differ as to harmfulness. (See, for example, Carstensen J.M., Pershagen G. and Eklund G., Mortality in relation to cigarette and pipe smoking: 16 years of observation of 25,000 Swedish men. J. Epidemial Community Health 1987, 41, 166-172). In addition, overlapping occurs in the use of different types of smoking implements. Among other things, the greater part of sold smoking tobacco is for rolling cigarettes.

b) A special set of texts for large cigarette packages (cartons)

Commentary: In the special reasons given for the warning text law, the following is stated (bill 1975/76:49): "Marking should, of course, take place on the package in which the product normally is sold to the consumer. Special cases are, for example, that a package contains a number of packs of cigarettes. In the same way, there are individually packed cigarettes in larger packages. In such cases, the supervisory authority may decide which of the packages shall be marked." Larger packages of cigarettes (cartons), to a greater extent, have acquired to character of consumer packages, which - among other things - can be seen in the marketing of the tobacco

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industry (advertisements with cartons of cigarettes, especially carton discounts). Therefore, even these packages should be marked.

c) A special set of varying texts for so-called smokefree tobacco products (including a text for dry, so-called smelling snuff)

Commentary: Knowledge has also increased in regard to so-called smokefree tobacco products. Even here, there is a need to change the warning text system so that a greater amount of information can be included.

2. Strengthening the attention and reading value of the warning texts

(Note! Only applies to texts on tobacco products that are intended to be smoked)

a) The square the warning text is placed in is to be increased substantially, from the present 5x2 cm to approximately 5x6 cm. The new warning texts on large cigarette packages are to be made even larger, approx. 15x6 cm.

b) Only the colors black and white are allowed to be used in the square of the warning text.

c) The warning text is to even include a symbol.

d) Larger type is to be used in proportion to the increased size of the square the respective length of the text.

e) Very short texts alternate with longer texts that also include explanations and comments.

Commentary: In paagraph 1 of the law about warning text and declaration of contents on tobacco products (1975:1154), the following is stated: "The Government or authority that the government appoints decides how the warning text is to be worded and what information shall be made available in the declaration of contents. In connection with this, it may be established how the text and the declaration shall be designed and be put on the package." In the prefaces (bill 1975/76:49) the following is stated, among other things: "It is important that the marking be put on the package in a clear and conspicuous way. The text should be brief, easy to read and unambiguous. It should also be possible to prescribe that a symbol be placed in connection with the text."

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3. New texts for cigarettes (consumer packages with the exception of packages containing 200 cigarettes (cartons), cigars, cigarillos, pipe tobacco and rolling tobacco.

1. Smoking kills more than 20 persons a day in Sweden.

Commentary: The number of premature deaths caused by smoking, in different studies, has been estimated at between 8,000 and 13,000 per year (see Isacsson S-O. Tobak och hälsa (Tobacco and health). Tobak och prevention (Tobacco and prevention). *SPRI rapport* 85, 1981). An example of such a study is Hjalm K. Isacsson S-O, Lindgren B. Widehusen L. Vad kostar tobaksbrukets medicinska skadeverkningar? (What do the medically harmful effects of the use of tobacco cost?) *Läkartidningen* (Physicians' Magazine) 1985: 82:2978-2981.

2. It always pays to quit smoking - regardless of how long you have smoked. The risk of cardiovascular disorders and cancer becomes less than if you continue smoking.

Commentary: See the Cancerkommittée, Cancer: orsaker, förebyggande mm (Cancer: causes, prevention etc) Stockholm: allmänna förlaget, 1984 (SOU 1984:67) and Svärdsudd K. Rökning och kardiovaskular sjukdom, epidemiologi och mekanismer (Smoking and cardiovascular disease, epidemiology and mechanisms). *Läkartidning* 1987, 84:3590 - 3593.

3. Tobacco smoke contains arsenic, lead, cadmium and many other harmful substances.

Commentary: See Cancerkommittée, above (p 137)

4. A heart attack before the age of 50 strikes almost only smokers

Commentary: See Eriksson C-G, Tibblin G. Tobaksrökning och hjärt-kärlsystemet (Tobacco smoking and the cardiovascular system) Tobaksrökning eller hälsa(Tobacco smoking or health). Tobakens medicinska skadeverkingar (The medically harmful effects of tobacco). The committee of the National Board for Health and Welfare, Stockholm: Liber förlag 1979)

5. Smoking is the main cause of cancer of the lungs, throat and the larynx. In addition, the risk of cancer of the lips, mouth and esophagus, pancreas and urinary bladder increases.

Commentary: See Larson L-G. Tobak och cancer - sambanden övertygande (Tobacco and cancer - the ties convincing). *Läkartidningen* 1988, 85:2858 - 2863.

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6. The number of women who die of lung cancer is increasing dramatically. This is due to smoking.

Commentary: See Larsson, L-G and others, above.
Eklund G, Gunnarsson T, Sparén F, Adami H-O. Cancerregistret som epidemiologisk kunskapskälla (The cancer register as an epidemiologic source of knowledge) *Läkartidning* 1988; 85:2338 - 2342.

7. Many smokers who have a perpetual morning cough think that this is normal. It isn't. Most often, it is due to smoking.

Commentary See Eriksson C-G, Tibblin G. Tobaksrökning och andningsorganer (Tobacco smoking and the respiratory organs). Tobaksrökning eller hälsa. Tobakens medicinska skadeverkningar. The committee of the National Board of Health and Welfare for health information. Stockholm: Liber förlag, 1979.

8. Eight of ten patients with cancer of throat are smokers.

Commentary: See Larsson L-G, above.

9. The ulcers of smokers heal worse and recur easier.

Commentary: See Graffner H, Lindell G. Rökning och ulcus - kräv rökstopp innan terapi inleds (Smoking and ulcers - demand that smoking stops before therapy is begun) *Läkartidning* 1987; 84:3571 - 3572.

10. Smoking contributes to the skeleton becoming more fragile. Older women are especially exposed.

Commentary: See Eliasson M. Tobaksrökningens effekter på endokrina organ - en överskt (The effects of smoking tobacco on the endocrine organs - a survey. *Läkartidningen* 1988; 85:4098 - 4100.

11. Both smoking and using moist snuff increase the risk of cancer of the mouth. Smoking also contributes to loosening of the teeth.

Commentary: See Larsson L-G *et al.* above
Preber H. Rökning och behandling av parodontit (Smoking and treatment of periodontosis). Tandhälsa, tandvård och rökning. Leo läkemedel, Helsingborg 1988.

12. Most people with asthma have hypersensitive bronchial tubes. Your tobacco smoke can aggravate the complaint.

Commentary: See Allergiutredning. Att förebygga allergi/överkänslighet (The report of the Allergy Commission. Preventing allergies/hypersensitivity). Stockholm: Allmänna förlaget 1989 (SOU 1989:76)

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13. Children who are exposed to tobacco smoke more often suffer allergic complaints.

Commentary: See The Report of the Allergy Commission

14. Do the children often have coughs? Children who are exposed to tobacco smoke more often suffer serious infections of the respiratory passages.

Commentary: See Pershagen G. Hälsorisker vid passiv rökning (Health risks with passive smoking) *Läkartidning* 1986; 83:1049 - 1055; Friberg L. Passiv rökning - en hälsofara (Passive smoking - a health hazard) *Läkartidning* 1987; 84:3573; and Fielding J.E., Phenow K. J. Health Effects of Involuntary Smoking. New England Journal of Medicine. Vol. 319, NO. 22, Dec 1, 1988.

15. Smoking creates addiction. Nicotine causes a physical addiction in a similar way as heroin or cocaine.

Commentary: See US Department of Health and Human Services. The Health Consequences of Smoking: Nicotine Addiction. A Report of the Surgeon General. Rockville MD, USA 1988 (DHSS Publication No. (CDC 83-8406).

16. Smoking during pregnancy retards the growth of the foetus and increases the risk of miscarriage.

Commentary: See Ahlström G. Bäst för fostret/det nyfödda barnet om kvinnan inte röker under graviditeten (Best for the foetus/the newborn baby if the woman does not smoke during pregnancy). *Läkartidning* 1988; 85:849 - 852.

All of the above texts shall be used on cigarette packs (however, not cartons, cf below).

For a pack of pipe tobacco or rolling tobacco, the same texts with the exception of texts 6, 10, 11 and 16 are to be used.

For packs of cigars/cigarillos texts 1, 2, 3, 4, 5 and 12 are prescribed.

Commentary: The number of texts for respective type of product corresponds to the views that have been put forward by the Swedish Tobacco Manufacturers' Association.

4. New texts for large cigarette packages (cartons)

17. Stefan started smoking as early as when he was in junior high school. By the age of twenty, he was smoking a pack a day. Twenty years later, he was still perfectly healthy, even if he was out of shape. But one afternoon, he suddenly collapsed at work. Before the end of the day

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he was dead. Cause of death: heart attack. He was 40 years old.

Smoking causes a five to ten times greater risk of dying of a sudden heart attack in one's younger years.

Commentary: The introductory example is based on the death of a real person whose identity, of course, has been kept secret but is known to the members of the special consultative group of the National Board of Health and Welfare. Certain details have been changed to make identification more difficult. Concerning the connection smoking - sudden death, see Svärdsudd K. *op cit.*

18. Karin started to smoke when she was eighteen. She smoked almost a pack a day. She tried to quit many times, but that was difficult since many of her friends at work smoked. Just prior to her 37th birthday, she started to cough more than usual and started loosing weight. Karin went to a doctor who discovered a discoloration on the lung when it was x-rayed. Further examination revealed a type of lung cancer that almost exclusively afflicts smokers and which is very difficult to cure. Half a year later, Karin was dead.

The number of women who die of lung cancer is increasing dramatically. This is due to smoking

Commentary: The introductory example is based on the deaths of a two real persons whose identities are known to the members of the consultative group. Information about the two cases has been combined to order to make identification more difficult. Concerning the connection smoking - increase prevalence of lung cancer among women, see commentary to text 6, above.

19. Smoking is the main cause of cancer of the lungs, throat and the larynx. In addition, smoking increases the risk of cancer of the lips, mouth, esophagus, pancreas and urinary bladder. New research findings indicate that the risk of cancer of the kidneys and the cervix also increases because of smoking.

Commentary: See commentary to text 5, above.

20. Your smoking can harm others!
Children who are exposed to tobacco smoke more often suffer serious infections of the respiratory passages.
Many people suffer from allergies and other hypersensitivity. The tobacco smoke of others can aggravate the complaint.
Long-term passive smoking can increase the risk of lung cancer.

Commentary: See commentary to texts 12 and 14, above.

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5. New texts for snuff and tobacco packed in individual portions

21. Snuff and tobacco packed in individual portions contain cancer-causing substances, mainly so-called nitrosamines.

Commentary: See The National Board of Health and Welfare. Snus - en hälsorisk (Snuff - a health hazard). Rapport från ett expertmöte. Stockholm 1988 (PM 1988:4).

22. Both using moist snuff and smoking increase the risk of cancer of the mouth.

Commentary: See commentary to text 15, above.

23. Moist snuff and tobacco packed in individual portions cause a nicotine addiction that is as strong as that of cigarettes.

Commentary: See commentary to text 15, above.

24. Moist snuff and tobacco in individual portions can cause injuries to the mucous membranes of the mouth and to the gums.

Commentary: See Azel T. Snusning och dess skadeverkningar (The use of snuff and its harmful effects) Tobaksrörning eller hälsa. Tobakens medicinska skadeverkningar. The committee of the National Board of Health and Social Welfare for health information. Stockholm: Liber förlag, 1979.

For so-called smelling snuff only text 21 is prescribed.

Commentary: Regarding the reason for not exempting smelling snuff from the requirement for having a warning text, see Smokeless Tobacco Control, World Health Organisation, Technical Report Series 773, Geneva 1988.

SOME SPECIAL QUESTIONS

From the tobacco industry it has been advanced - without closer explanation - that certain of the new texts would be in conflict with the Freedom of the Press Act and the law concerning warning texts. Such arguments were heard by the government when the warning texts that are now in effect were implemented. The government at that time (10 April 1986, decision number 9) stipulated a number of warning texts that - beyond the stipulated health warning - contained clarifications, comments etc. Hence, it can be seen that even concrete information, exemplifications, and to a certain extent, direct advice in the form of exhortations should be able to be included in warning

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texts. However, a text may not lack explicit and concrete information about health risks of tobacco. Neither is it allowed to be designed as a general exhortation to refrain from smoking. All of the texts that are prescribed at this time fulfill these demands.

The tobacco industry has also argued that the new texts are in conflict with the law concerning warning texts since the increased size of the square of the warning text upsets "the balance" between the health warning and the commercial message on the package. In regards to "balance" it can be stated that the square (with the new size) takes up slightly more than a fifth of the *total* surface of the package (and closer to two fifths of the combined surface of the front and back sides). In discussions with the Consumer Board, the tobacco industry has accepted, regarding advertising rules, that the warning text shall take up 20% of the surface in tobacco advertisements.

These questions can once again become issues to be heard by the government, if some tobacco company would like to appeal the decision of the National Board of Health and Welfare. In such a case, the appeal could contribute to increased clarity and even to possibly finding out that there is a need to review legislation concerning the warning texts. Such a review could then very suitably take place in connection with the proposal about a special tobacco law that is most likely will be discussed in Parliament during the spring of 1991.

In addition, the tobacco industry has stated that the National Board - if the texts are changed - should implement the texts that will apply within the EC. A difficulty is, however, that the EC directive in force prescribes marking on both the front and back sides of the cigarette pack. As early as 1976, when the Swedish warning text system was developed, the National Board planned to prescribe marking on both the front and back sides. The legal division of the Ministry of Health and Social Affairs argued, however, at that time that the Swedish law concerning warning texts did not allow for more than one text per pack. Thus, it was held that the warning texts of the EC could not be implemented without a change in the law.

It can be added that Sweden is not yet a member of the EC. It is said that a possible EES agreement will allow EFTA countries to keep their own legislation in the areas of health and the environment, as long as this is stronger than comparable EC legislation.

From a Swedish point of view, the warning texts of the EC do not seem to be better than the present Swedish ones. The factual content that is contained within the EC system is less inclusive, and has for a long time been included in the Swedish warning texts. In other words,

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the EC texts do not mean that information for the consumers would be improved.

Finally, it can be noted that the EC directive concerning warning texts is not included as a part of the work to eliminate technical trade barriers within the EC (the so-called inner market) but instead belongs to the anti-cancer program of the EC. Even in the future, the EC texts will to a certain extent constitute trade barriers since the texts are to be designed in the language of the individual countries. Thus, a totally free movement for packaged tobacco products will not take place even within the EC.

Seen in the light of this, a possible future adaptation to the marking rules of the EC should be deferred until Sweden possibly has become a member.

II. DECLARATIONS OF CONTENTS

In connection with the decision about the new warning texts, some minor changes in the rules concerning declarations of contents have taken place. They deal mainly with three questions.

DECLARATION OF "TAR" AND NICOTINE RESPECTIVELY

In Sweden, up until now the declaration of contents - because of "historical" reasons - has both stated the amount of "tar" including nicotine and also separately has stated the amount of nicotine in the smoke from each cigarette.

In the rules for the declarations of contents that have been set down for the EC, however, it is prescribed that the amount of "tar" shall be stated excluding nicotine ("raw anhydrous nicotine-free condensate of smoke"). The nicotine is then stated separately. The EC rules correspond to dominating international practice up until this time.

Sweden, in this respect, should adapt its rules to the EC. The public notice of the National Board of Health and Welfare is thus changed in this matter. The change on the pack should take place during 1991 at the same time that the statement of the mean average in the declaration of contents is brought up to date (which usually takes place by decision of the National Board during February).

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UPDATING THE STATEMENT OF MEASURING METHODS

The amounts of tar, nicotine and carbon monoxide are determined by internationally standardized methods. These methods are at this time in the process of being updated. The public notice of the National Board should be

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continually changed so that it states the current methods.

MORE FLEXIBLE LAYOUT

Up until this time, the public notice of the National Board has presented a pattern for how the declaration of contents is to be set up on the pack. Taking into consideration that the informative value of the declaration of contents for the consumer appears to be less than it was in the 1970s, the National Board can - without changing the rules about what information shall be stated in the declaration - now refrain from regulating the layout of the declaration in detail. The declaration of contents is part of the commercial message of the package. More flexible rules for this layout can, to a certain extent, compensate for the new warning texts taking up a larger percentage of the surface of the package than up until now.

Change in public notice (SOSFS 1976:23) about warning texts and declaration of contents on tobacco products.

Paragraph 3
The declaration of contents on cigarette packages shall include information about:

the content in the smoke of "tar" (raw condensate excluding nicotine and water), nicotine and carbon monoxide calculated per cigarette in the package,

the average values for the content in the smoke of its separate parts as the Board stipulates according to paragraph 5. (Applies to all brands of cigarettes sold in the country).

Paragraph 4
No later than January 15th of each year, the manufacturer or the importer of those cigarette brands that are sold in the country shall report to the National Board information about the declared values for the content in the smoke of "tar", nicotine and carbon monoxide and about who is responsible for deviation between the declared and the actual values not being more than what is stated in paragraph 7.

Paragraph 6
The values that are stated in the declaration of contents and the information that, in accordance with paragraph 4 shall be presented to the National Board shall be determined by the methods mentioned below or by methods that give the same results as these.

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Tests:

ISO 8243 (1) Cigarettes - Sampling

Methods of analysis:

ISO 3402 (1): Tobacco and tobacco products - Atmosphere for conditioning and testing.

ISO 3308 (1): Routine cigarette-smoking machine - Definitions and standard conditions

ISO 4387 (1): Cigarettes - Determination of total and nicotine-free dry particulate matter using a routine analytical cigarette-smoking machine - Determination of total particulate matter and preparation for water and nicotine measurements.

ISO 10315 (1): Cigarettes - Determination of nicotine in smoke condensates - Gas-chromatographic method

ISO 10362 (1): Cigarettes - Determination of water in smoke condensates - Gas chromtographic method

ISO 8454 (1): Cigarettes - Determination of carbon monoxide in the vapour phase of smoke (NDIR method).

The amounts are stated in milligrams, "tar" and carbon monoxide with a difference of plus minus one milligram and nicotine with a difference of plus minus 0.1 milligrams. Values below 0.5 mg for "tar" and carbon monoxide respectively, below 0.05 mg nicotine for nicotine are rounded off upwards to 1.0 mg and 0.1 mg respectively

(1) Standard set up by the International Organization for Standardization. Can be ordered through SIS - the Standardization Commission in Sweden, Box 3295, 103 66 Stockholm. Telephone 08 - 613 52 00.

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